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(2) *Cattle*—

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 568 to 757		Beef and nonlactating dairy cattle: For the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of beef and nonlactating dairy cattle, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product.	000986
(ii) 568 to 757	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency; and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter.	000986
(iii) 568 to 757	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii;* and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d) of this chapter.	000986

[61 FR 68148, Dec. 27, 1996; 62 FR 15391, Apr. 1, 1997, as amended at 64 FR 13679, Mar. 22, 1999; 65 FR 76930, Dec. 8, 2000; 67 FR 21997, May 2, 2002; 69 FR 78306, Dec. 30, 2004; 76 FR 76894, Dec. 9, 2011; 77 FR 60623, Oct. 4, 2012; 78 FR 19987, Apr. 3, 2013]

§ 558.625 Tylosin.

(a) *Specifications.* Type A medicated articles containing tylosin phosphate.

(b) *Approvals.* Type A medicated article levels of tylosin granted to firms as

sponsor(s) and identified by drug listing numbers in § 510.600(c) of this chapter for the specific usage indicated in paragraph (f) of this section.

(1) To 000986: 10, 40, 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(2)–(4) [Reserved]

(5) To No. 051311: 0.4, 0.8, 1, and 8 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 10 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(6)–(9) [Reserved]

(10) To No. 012286: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (vi) of this section.

(11)–(24) [Reserved]

(25) To 066104: 4, 8, and 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20 and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(26)–(32) [Reserved]

(33) To 034936: 0.8 and 2 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 4, 8, and 10 grams per pound, paragraphs (f)(1)(i), (iii), (iv), and (vi) of this section; 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section; 100 grams per pound, paragraphs (f)(1) (i), (ii), (iii), (iv), and (vi) of this section.

(34) [Reserved]

(35)–(38) [Reserved]

(39) To 061623: 10 grams per pound, paragraph (f)(1)(vi)(*a*) of this section.

(40)–(47) [Reserved]

(48) To 017790: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(49)–(53) [Reserved]

(54) To 054771: 5, 10, 20, and 40 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(55)–(77) [Reserved]

(78) To 050972: 0.36, 0.4, 0.72, and 0.8 gram per pound, paragraph (f)(1)(vi)(*a*) of this section; 1 gram per pound, paragraphs (f)(1)(vi) (*a*), (*b*), and (*d*) of this section.

(79)–(84) [Reserved]

(85) To 047126: 10, 40, and 100 grams per pound, paragraphs (f)(1) (i) through (vi) of this section.

(86)–(88) [Reserved]

(89) To 048164: 5, 10, 20, and 40 grams per pound, paragraph (f)(1) (i) through (vi) of this section.

(90) No. 016592: 100 grams per pound for use as in paragraph (f) of this section.

(c) *Special considerations.* (1) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

(i) For liquid feeds stored in recirculating tank systems: Recirculate immediately prior to use for not less than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for not less than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) Tylosin liquid Type B medicated feeds used to make Type C medicated feeds for cattle may be manufactured from tylosin Type A medicated articles according to the following mixing directions:

(i) [Reserved]

(ii) Maintain a pH between 4.5 and 6.0.

(3) Tylosin liquid Type B medicated feeds must bear an expiration date of 31 days after the date of manufacture.

(d) [Reserved]

(e) *Related tolerances.* See § 556.740 of this chapter.

(f) *Conditions of use.* (1) It is used in animal feeds as follows:

(i) *For beef cattle*—(*a*) *Amount per ton.* 8–10 grams.

(*b*) *Indications for use.* For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes.*

(*c*) *Limitations.* As tylosin phosphate; each animal must receive not more than 90 milligrams per day and not less than 60 milligrams per day; feed continuously as sole ration.

(ii) *Broiler chickens*—(*a*) *Amount per ton.* Tylosin, 800–1000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24–48 hours at 3 to 5 weeks of age.

(iii) *Chickens*—(*a*) *Amount per ton.* Tylosin, 4–50 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate.

(iv) *Laying chickens*—(*a*) *Amount per ton.* Tylosin, 20–50 grams.

(*b*) *Indications for use.* For improved feed efficiency.

(*c*) *Limitations.* As tylosin phosphate.

(v) *Replacement chickens*—(*a*) *Amount per ton.* Tylosin, 1,000 grams.

(*b*) *Indications for use.* To aid in the control of chronic respiratory disease caused by *Mycoplasma gallisepticum.*

(*c*) *Limitations.* As tylosin phosphate; withdraw 5 days before slaughter; administer in feed to chickens 0 to 5 days of age, follow with second administration in feed for 24 to 48 hours at 3 to 5 weeks of age.

(vi) *Swine*—(*a*) *Amount per ton.* Tylosin, 10–100 grams.

(*1*) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(*2*) *Limitations.* As tylosin phosphate; continuous use as follows: *Grams per ton:* 20–100, prestarter or starter; 20–40, grower; 10–20, finisher.

(*b*) *Amount per ton.* Tylosin, 40 or 100 grams.

(*1*) *Indications for use.* For control of swine dysentery associated with *Brachyspira hyodysenteriae*, and for control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* Use 100 grams per ton for at least 3 weeks followed by 40 grams per ton until market weight; as tylosin phosphate.

(*c*) *Amount per ton.* Tylosin, 40–100 grams.

(*1*) *Indications for use.* For the treatment and control of swine dysentery associated with *Brachyspira hyodysenteriae* and for the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* Administer as tylosin phosphate in feed for 2 to 6 weeks, immediately after treatment with tylosin tartrate in drinking water as in § 520.2640(d)(3) of this chapter.

(*d*) *Amount per ton.* Tylosin, 100 grams.

(*1*) *Indications for use.* Maintaining weight gains and feed efficiency in presence of atrophic rhinitis.

(*2*) *Limitations.* As tylosin phosphate.

(vi) Pyrantel tartrate in accordance with § 558.485.

(*e*) *Amount per ton.* Tylosin 100 grams.

(*1*) *Indications for use.* For the control of porcine proliferative enteropathies (PPE, ileitis) associated with *Lawsonia intracellularis.*

(*2*) *Limitations.* As tylosin phosphate, administer for 21 days.

(2) Tylosin may also be used in combination with:

(i) Decoquinate and monensin as in § 558.195.

(ii) Hygromycin B as in § 558.274.

(iii) Melengestrol acetate alone or in combination with certain ionophores as in § 558.342.

(iv) Monensin as in § 558.355.

(v) Narasin as in § 558.363.

(vi) Pyrantel tartrate as in § 558.485.

(vii) Ractopamine alone or in combination as in § 558.500.

(viii) Salinomycin as in § 558.550.

(ix) Zilpaterol alone or in combination as in § 558.665.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.625, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at *www.fdsys.gov.*

§ 558.630 Tylosin and sulfamethazine.

(a) *Specifications.* Type A medicated articles containing equal amounts of tylosin phosphate and sulfamethazine, available in concentrations of 4, 5, 10, 20, or 40 grams each, per pound.

(b) *Approvals.* See sponsor numbers in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 000986: 10 or 40 grams per pound each for use as in paragraph (e)(2)(i) of this section.

(2) [Reserved]